QUINN EMANUEL URQUHART & SULLIVAN, LLP
Thomas D. Pease (NJ Bar No. 055421994)
Peter Calamari (*pro hac vice* application pending)
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000 (Phone)
Ethan C. Glass (*pro hac vice* application pending)
Michael D. Bonanno (*pro hac vice* application pending)
1300 I Street NW, Washington, DC 20005
(202) 538-8000 (Phone)
Attorneys for Plaintiff RareGen, LLC

ALSTON & BIRD LLP
Jenny Kramer (NJ Bar No. 014372001)
90 Park Avenue 15th Floor
New York, NY 10016
(212) 210-9400 (Phone)
Michael P. Kenny (*pro hac vice* application pending)
Matthew D. Kent (*pro hac vice* application pending)
Allison S. Thompson (*pro hac vice* application pending)
Jonathan D. Parente (*pro hac vice* application pending)
1201 West Peachtree Street, Suite 4900
Atlanta, GA 30309
(404) 881-7000 (Phone)
Attorneys for Plaintiff Sandoz Inc.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Sandoz Inc. and RareGen, LLC *Plaintiffs*, v. United Therapeutics Corporation and Smiths Medical ASD, Inc. *Defendants*.	Case No. 3:19-cv-10170-BRM-LHG **MEMORANDUM IN SUPPORT OF PLAINTIFFS' APPLICATION FOR AN ORDER TO SHOW CAUSE WHY (1) EXPEDITED DISCOVERY SHOULD NOT BE GRANTED; AND (2) A SCHEDULING ORDER SHOULD NOT BE ISSUED**

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

Cases

Rules

PRELIMINARY STATEMENT

This antitrust case concerns a monopolist's efforts to thwart generic competition and maintain the price of a life-supporting drug at artificially inflated levels. Specifically, Defendants United Therapeutics Corporation ("United Therapeutics") and Smiths Medical ASD, Inc. ("Smiths") are unlawfully blocking Plaintiffs Sandoz Inc. ("Sandoz") and RareGen, LLC ("RareGen") from competing against United Therapeutics' brand name treprostinil drug ("Remodulin®") with a generic form of treprostinil.

Treprostinil injections are used to treat patients with a serious heart and lung condition called pulmonary arterial hypertension ("PAH"). Defendants control one of the consumables that are needed to deliver treprostinil injections under a patient's skin (*i.e.*, subcutaneous injections). Those consumables, called "cartridges," are a critical component of a subcutaneous treatment program because a PAH patient cannot receive subcutaneous injections of treprostinil without them. Defendants have used their control over cartridges to insulate Remodulin® from competition with Plaintiffs' generic treprostinil product by forbidding anyone from using cartridges to administer generic treprostinil treatments. There is no medical justification for Defendants' exclusionary conduct. Defendants are the only beneficiaries of their anticompetitive scheme, and their collective gains come at the expense of Plaintiffs and the patients who could otherwise receive lower-cost,

generic treprostinil injections instead of more expensive Remodulin® treatments.

Although the anticompetitive effect of Defendants' conduct is clear, the exact details of Defendants' secret arrangement are not publicly known. Until December 2018, cartridges used to administer treprostinil by subcutaneous injection, which are manufactured by Smiths, were available without any restrictions on their use. Indeed, before Plaintiffs were preparing to launch their generic product, Smiths publicly touted that the cartridges were "compatib[le] with a wide range of medications." But as Plaintiffs inched closer to launching a cheaper, generic product that would directly compete with Remodulin®, something changed as a result of a secret agreement between United Therapeutics and Smiths. United Therapeutics advertised that Smiths cartridges are "unique to Remodulin." And Smiths approached specialty pharmacies, which are the only pharmacies that dispense treprostinil administered through injections, to tell them that they could only acquire and dispense cartridges for use with Remodulin®. Through their anticompetitive actions, Defendants have stifled the entry of Plaintiffs' generic product and maintained the price of Remodulin® at artificially high levels—costing the healthcare system tens to hundreds of millions of dollars each year.

Before bringing this suit, Plaintiffs pursued a commercial agreement with Smiths that would remove the current cartridge restrictions, but those efforts were unsuccessful. Smiths refused to entertain any proposal that would allow Plaintiffs

to obtain cartridges and start immediately offering patients a generic alternative to Remodulin® for subcutaneous injections. Left with no other option, Plaintiffs brought this case to put a stop to Defendants' anticompetitive conduct and open up the market for meaningful competition.

Plaintiffs intend to promptly move for a preliminary injunction to obtain immediate relief from Defendants' anticompetitive restrictions and enjoin any restrictions on the specialty pharmacies' ability to dispense cartridges for use with generic treprostinil. Information that will be relevant to that motion, however, remains exclusively in Defendants' hands. For that reason, Plaintiffs respectfully ask the Court to enter an order that requires Defendants to show cause as to why (1) expedited discovery should not be ordered; and (2) a scheduling order concerning Plaintiffs' forthcoming preliminary injunction motion should not be issued. As explained below, there is good cause to proceed with expedited discovery and the preliminary injunction schedule requested by Plaintiffs.

FACTUAL BACKGROUND

Patients with PAH need specific medical devices (infusion pumps, together with single-use cartridges that are specifically designed for the infusion pumps) to receive subcutaneous injections of a drug called treprostinil. The CADD-MS® 3 pump and its associated cartridges, which are both manufactured exclusively by Smiths, are the only medical devices used in the United States today to administer

subcutaneous treprostinil injections. Declaration of Damian deGoa ("deGoa Decl.") ¶ 10.

On March 25, 2019, Plaintiffs entered the market with the first generic form of treprostinil that can be administered through subcutaneous injections. deGoa Decl. ¶ 17. Just before the commercial launch of Plaintiffs' generic treprostinil, Smiths began telling specialty pharmacies that it would not sell them CADD-MS® 3 cartridges for use with generic treprostinil injections. *Id.* ¶¶ 12-13. Specialty pharmacies typically maintain a limited inventory of cartridges (usually enough to cover patient needs for up to four weeks), and Smiths told them in early 2019 that any additional cartridges they obtained could only be used exclusively with Remodulin®. deGoa Decl. ¶¶ 12-13.

While the exact terms of Defendants' exclusionary arrangement remain shielded in secrecy, United Therapeutics recently confirmed in a public SEC filing that Defendants reached an agreement under which all cartridges manufactured by Smiths can be "use[d] with branded Remodulin only." Declaration of Ethan Glass ("Glass Decl."), Ex. A (United Therapeutics 10-K), at 6. On its website, United Therapeutics is now promoting that the CADD-MS® 3 pump and cartridges are "unique to Remodulin." Glass Decl., Ex. B, at 1. And for its part, Smiths has maintained that it cannot sell cartridges to Plaintiffs (or anyone else who intends to use them to administer generic treprostinil treatments) because "[a]ll remaining units

that have been manufactured or that can possibly be manufactured have been contractually committed to [United Therapeutics] or to [United Therapeutics]-authorized customers." Glass Decl., Ex. C, at 6. As a result of these restrictions, neither specialty pharmacies nor patients can administer generic treprostinil treatments through subcutaneous injections. deGoa Decl. ¶¶ 12-14, 17.

Until December 2018, none of these restrictions existed. Treprostinil can only be obtained with a prescription, and the only two pharmacies that dispense treprostinil for administration through injection in the United States are Accredo Health Group, Inc. ("Accredo") and CVS Specialty Pharmacy ("CVS Specialty"). deGoa Decl. ¶ 7. Prior to 2019, there was no generic alternative to Remodulin® in the market, and, until December 2018, Accredo and CVS Specialty were able to purchase CADD-MS® 3 cartridges directly from Smiths (or an authorized distributor) without any limitations. Indeed, the brochure for the CADD-MS® 3 pump, which was still available on the Smiths website in March 2019, promotes the fact that its "polypropylene cartridge material" is "compatib[le] with a wide range of medications." Glass Decl., Ex. D.

There is no medical necessity for the restrictions Defendants have placed on Smiths' cartridges. Instead, Defendants have imposed them for one reason: to protect United Therapeutics' bottom line. Since the FDA first approved Remodulin® for subcutaneous injections in the United States in 2002, Remodulin® has been the

only drug available in the United States for subcutaneous treatment of PAH. Glass Decl., Ex. E, at ¶ 880 ("Remodulin is the only prostacyclin in the U.S. market that can be administered through subcutaneous infusion, which has certain advantages over intravenous infusion."). During the last three calendar years alone, Remodulin® was responsible for $599.0 million, $670.9 million, and $602.3 million in net product sales for United Therapeutics, which represented more than 35% of the company's total revenues in each of those years. Glass Decl., Ex. A (United Therapeutics 10-K), at 5-6.

According to United Therapeutics, Remodulin® accounts for more than 70% of the market for parenterally administered (*i.e.*, injected) prostacyclin treatments for PAH, and more than half of the patients being treated for PAH with Remodulin® are receiving Remodulin® through subcutaneous injections. Glass Decl., Ex. A (United Therapeutics 10-K), at 7; Ex. F (United Therapeutics 3Q 2013 Earnings Call), at 8; Ex. E, at ¶ 879 ("Remodulin represents over 70 percent of the parenteral prostacyclin market, including generics."). Thus, by unlawfully preventing Plaintiffs from accessing the subcutaneous segment of the market, Defendants have insulated United Therapeutics' dominant position in the market from meaningful generic competition and forced PAH patients to continue paying exorbitant prices for the medication they need.

Before filing this suit, Plaintiffs approached Smiths to negotiate a commercial

arrangement under which Plaintiffs would receive (1) a license to manufacture their own cartridges based on the Smiths design; (2) a license to the information necessary to manufacture the cartridges (including the identity of the resin used by Smiths to manufacture the cartridges and the identity of its resin supplier); and (3) an interim supply of cartridges from Smiths to be used with generic treprostinil until Plaintiffs could transition to a supply of cartridges produced by another manufacturing partner. deGoa Decl. ¶ 15. Smiths rejected Plaintiffs' proposal on April 3, 2019. *Id*.

ARGUMENT

"[M]atters of docket control and conduct of discovery are committed to the sound discretion of the district court." *In re Fine Paper Antitrust Litig.*, 685 F.2d 810, 817 (3d Cir. 1982). Accordingly, the Court may order early and expedited discovery at its discretion. Fed. R. Civ. P. 26(d). "This will be appropriate in some cases, ***such as those involving requests for a preliminary injunction*** or motions challenging personal jurisdiction." Fed. R. Civ. P. 26(d) cmt. (1993 amendments) (emphasis added). Where expedited discovery is sought to support a preliminary injunction motion, this Court should permit such discovery if "the requests are reasonable under the circumstances." *Better Packages, Inc. v. Zheng*, Civil Action No. 05-4477(SRC), 2006 WL 1373055, at *2 (D.N.J. May 17, 2006); *see also Sawhorse Enters., Inc. v. Church & Dwight Co.*, Civil Action No. 12-6811 (FLW), 2013 WL 1343608, at *5 (D.N.J. Apr. 3, 2013) ("This test weighs the need for

expedited discovery by considering the overall administration of justice against the prejudice to the responding party."); *Nest Int'l, Inc. v. Balzamo*, Civil Action No. 12-2087 (JBS/KMW), 2012 WL 1584609, at *2 (D.N.J. May 3, 2012) ("The Court finds good cause to order at least some expedited discovery, as it appears reasonably necessary to enable this Court to judge the parties' interests and respective chances for success on the merits at a preliminary injunction hearing."); *Chubb Ina Holdings Inc. v. Chang*, Civil Action No. 16-2354 (FLW)(DEA), 2016 WL 3470291, at *4 (D.N.J. June 24, 2016) (applying the "good cause" standard).

For the reasons explained below, there is good cause for the discovery and scheduling order Plaintiffs have requested.

I. With Narrowly Tailored Discovery, Plaintiffs Will Show a Preliminary Injunction Is Necessary to Preserve Competition and Its Benefits to the Public

"Four factors are considered in determining whether to grant a preliminary injunction: (1) whether the movant has a reasonable probability of success on the merits; (2) whether the movant will be irreparably harmed by denying the injunction; (3) whether there will be greater harm to the nonmoving party if the injunction is granted; and (4) whether granting the injunction is in the public interest." *Highmark, Inc. v. Upmc Health Plan, Inc.*, 276 F.3d 160, 170-71 (3d Cir. 2001). Even without the benefit of discovery, as explained below, it is clear that Defendants' conduct raises serious competitive and healthcare concerns that weigh heavily in favor of the

issuance of an injunction. Discovery is needed, however, to confirm the exact details of Defendants' unlawful conduct and agreements and ensure the Court is presented with a fulsome record in Plaintiffs' forthcoming motion for a preliminary injunction that addresses all relevant facts—including those that are only known to Defendants today.

A. Discovery Will Confirm Plaintiffs Are Likely to Succeed on the Merits

"When a monopolist's actions are designed to prevent one or more new or potential competitors from gaining a foothold in the market by exclusionary, i.e. predatory, conduct, its success in that goal is not only injurious to the potential competitor but also to competition in general." *LePage's Inc. v. 3M*, 324 F.3d 141, 159 (3d Cir. 2003). That is what has happened here. United Therapeutics is a monopolist, and in concert with Smiths, it has engaged in exclusionary conduct that inhibits generic competition.

Although there are differences between violations of Section 1 and Section 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, there are certain elements that overlap: (1) the possession of market power in the relevant antitrust market, and (2) anticompetitive conduct. *See*, *e.g.*, *LePage's Inc.*, 324 F.3d at 159 (foreclosure of "40% or 50% share usually required in order to establish a § 1 violation"); *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 306–07 (3d Cir. 2007) ("Liability under § 2 requires (1) the possession of monopoly power in the relevant market and

(2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.") (quotations omitted).

One relevant antitrust product market at issue here is no greater than subcutaneously injected teprostinil. Treprostinil is the only treatment for PAH that can be administered through both subcutaneous and intravenous injections (epoprostenol can only be administered intravenously). Glass Decl., Ex. A, at 6. Nearly 2,000 patients in the United States are currently being treated for PAH with subcutaneous Remodulin® injections. deGoa Decl. ¶ 9. Those patients have been prescribed Remodulin by their treating physicians and their treatment program relies on subcutaneous injections using the CADD-MS® 3 pump. Those patients will not switch to other PAH treatments in response to a small, but significant, and non-transitory increase in the price of subcutaneously injected treprostinil. Subcutaneously injected treprostinil therefore constitutes a relevant antitrust product market.

Another relevant antitrust product market affected by Defendants' conduct is no greater than injected prostacyclin-based treatments (treprostinil is a synthetic prostacyclin). As confirmed by United Therapeutics' own public statements, patients are prescribed injected prostacyclins because their treating physicians believe prostacyclin injections are the best form of treatment for their particular

symptoms. Glass Decl., Ex. G (United Therapeutics Q1 2017 Earnings Call), at 2; Ex. H (United Therapeutics Q4 2012 Earnings Call), at 2. And patients do not switch between various PAH treatments in response to changes in drug prices. Glass Decl. Ex. G, at 2 (whether patients "go onto Orenitram first and then Tyvaso, or Tyvaso first and then Remodulin, or straight to Remodulin" is "simply a consequence of their doctor's judgment as to how much prostacyclin they require and in what form"). Because injected prostacyclins have no reasonable substitutes, and patients do not substitute between injected prostacyclins and other PAH treatments in response to small changes in price, they represent a well-defined antitrust product market. *See Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co. (Doryx)*, 838 F.3d 421, 437 (3d Cir. 2016).

United Therapeutics has monopoly power in both of those relevant product markets. Before the entry of generic competition, United Therapeutics sold 100% of the treprostinil administered through subcutaneous injections in the United States, and as a result of the restrictions related to the CADD-MS® 3 cartridges, it continues to sell 100% of the treprostinil administered through subcutaneous injections in the United States. And according to United Therapeutics' own estimates, Remodulin® accounts for between 70% and 80% of all prostacyclins administered by injection. Glass Decl., Ex. F (United Therapeutics Q3 2013 Earnings Call), at 8; Ex. E, at ¶ 879 ("Remodulin represents over 70 percent of the parenteral prostacyclin market,

including generics."). Thus, United Therapeutics possesses monopoly power. *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 202-03 (3d Cir. 1992) (the defendant's 55% market share, far in excess of the share held by closest competitors, combined with evidence of high entry barriers, was sufficient to affirm finding of market power); *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 184 (3d Cir. 2005) (in an industry "consisting of 12-13 manufacturers," the defendant's "75%-80% market share on a revenue basis" and "67% on a unit basis" was sufficient to establish monopoly power).

Defendants also have engaged in anticompetitive conduct. Whether Defendants have conspired (triggering Section 1 liability) or United Therapeutics is acting unilaterally (triggering Section 2 liability), their exclusionary conduct has undeniably cut off Plaintiffs from a key part of the market, which is prima facie evidence of anticompetitive conduct. *See*, *e.g.*, *Dentsply*, 399 F.3d at 191 ("The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit."). Patients who have been prescribed subcutaneous injections are "locked in" to using the cartridges that Defendants control, *see Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 476 (1992), and Defendants have abused that control to limit patients' options. Because Smiths (the manufacturer of the cartridges) has agreed not to deal with anyone other than United Therapeutics (or purchasers specifically approved by

United Therapeutics), and specialty pharmacies have been forced to buy cartridges on the condition that they will only be used with Remodulin, patients receiving subcutaneous injections have no choice but to use Remodulin®.

United Therapeutics has completely foreclosed generic competition in a substantial portion of the market, and that is unlawful exclusionary conduct by a monopolist. *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 284 (3d Cir. 2012) ("[I]f the defendant occupies a dominant position in the market, its exclusive dealing arrangements invariably have the power to exclude rivals."); *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1065 (3d Cir. 1978) ("[T]he act of willful acquisition and maintenance of monopoly power was brought about by linking products on which [defendant] faced no competition . . . with a competitive product."). "By ensuring that the [specialty pharmacies] offer [Remodulin®] either as the only or dominant choice, [the restrictions] ha[ve] a significant effect in preserving [United Therapeutics'] monopoly." *Dentsply*, 399 F.3d at 191. Because Plaintiffs have been substantially foreclosed from challenging Remodulin® in the subcutaneous segment of the market, they have not been able to meaningfully challenge United Therapeutics' dominant market position. *ZF Meritor*, 696 F.3d at 286 ("Substantial foreclosure allows the dominant firm to prevent potential rivals from ever reaching the critical level necessary to pose a real threat to the defendant's business.") (quotations omitted).

There are no pro-competitive justifications for Defendants' conduct. *See Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 509 (2d Cir. 2004) ("[A]n exclusive dealing agreement that dedicated all supply to one buyer could freeze out competition to an extent that greatly outweighed any pro-competitive effects."); *Microbix Biosystems, Inc. v. Biowhittaker, Inc.*, 172 F. Supp. 2d 680, 693 (D. Md. 2000) (the anticompetitive effects of Defendants' exclusive supply agreement outweighed any pro-competitive virtues because the "purpose of the agreement was to assure that other groups could not utilize [the necessary material]") (quotations omitted). Smiths previously sold the cartridges without limitations, and, at least up until last month, Smiths continued to market through product brochures made available on its website that the cartridges are "compatib[le] with a ***wide range of medications***." Glass Decl., Ex. D (emphasis added). Plaintiffs understood from the specialty pharmacies as late as December 2018 that they planned to provide patients with access to generic treprostinil using their existing cartridges and new cartridges purchased through their existing suppliers. deGoa Decl. ¶ 11. But everything changed as Plaintiffs geared up for launch and Defendants implemented restrictions to prohibit cartridges from being used with any medication other than Remodulin®.

There is no justification for the breadth of the exclusionary restrictions that Defendants have imposed. Indeed, before bringing this suit, Plaintiffs sought to

purchase cartridges from Smiths and license the design to transition to its own manufacturing partner, but those efforts were rebuffed. deGoa Decl. ¶¶ 15-16.

B. Discovery Will Confirm Defendants' Conduct Is Causing Irreparable Harm to Plaintiffs

Without an injunction, Plaintiffs will suffer irreparable harm. Under Third Circuit law, the concept of irreparable harm includes "loss of goodwill, damage to reputation, and loss of business opportunities." *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012); *see also Kos Pharms., Inc. v. Andrx Corp.*, 369 F.3d 700, 726 (3d Cir. 2013). All of those matters are at stake in this case.

The inability of specialty pharmacies to obtain cartridges to use with generic treprostinil will result in irreparable harm to Plaintiffs' goodwill. "It would be impossible to estimate or compute [Plaintiffs'] damages for the loss of goodwill which [they] will suffer as a result of being unable to provide [customers with subcutaneous generic treprostinil]." *Bergen Drug Co. v. Parke, Davis & Co.*, 307 F.2d 725, 728 (3d Cir. 1962). Plaintiffs are breaking new ground by offering the first generic alternative to Remodulin®; they need to convince specialty pharmacies and patients that they can deliver not only a therapeutic equivalent for Remodulin®, but also the accompanying services and on-time supplies that are needed to support a full PAH treatment program. The perception that Plaintiffs will be unable to follow through on those commitments—especially with regard to their ability to serve the subcutaneous segment of the market—will inflict irrevocable damage to their

reputation and image, from which they will not be able to recover. *See, e.g.*, *Byrne v. Calastro*, 205 F. App'x 10, 16 (3d Cir. 2006) (damage to reputation and image can constitute irreparable harm).

C. Discovery Will Confirm Defendants Will Not Suffer Undue Prejudice from Competition with Plaintiffs

Should the Court issue a preliminary injunction, there would be no countervailing risk of substantial harm to Defendants. Defendants will still be able to sell cartridges and Remodulin® in competition with Plaintiffs. The only possible harm to Defendants is associated with their inability to enforce their unlawful pact, and it is black letter law that "the injury a defendant might suffer if an injunction were imposed may be discounted by the fact that the defendant brought that injury upon itself." *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 596 (3d Cir. 2002).

D. Discovery Will Confirm the Public Interest Weighs in Favor of the Issuance of an Injunction

"[T]he public interest would benefit from increased competition from [generic manufacturers]." *Otsuka Pharm. Co. v. Torrent Pharm. Ltd.*, 99 F. Supp. 3d 461, 507 (D.N.J. 2015). And, conversely, "the public interest would be particularly disadvantaged by permitting [United Therapeutics] to extend its market exclusivity" through unlawful restrictions that frustrate one of the principal goals of the Hatch-Waxman Act, which is to "encourage generic drug entry into the

marketplace." *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 240 (3d Cir. 2017); *see also In re Metoprolol Succinate Direct Purchaser Antitrust Litig.*, Civil Action Nos. 06-52 (GMS), 06-71(GMS), 2010 WL 1485328, at *1 (D. Del. Apr. 13, 2010) ("[O]nce the statutory patent protection and marketing exclusivity for these new drugs has expired, the public benefits from the rapid availability of lower priced generic versions of the innovator drug."). Every day that passes without a generic alternative to Remodulin® being made available for subcutaneous treatments maintains the price of Remodulin® at artificially inflated levels. In turn, those elevated costs will be borne by the public-at-large in the form of higher insurance costs.

There can be no dispute that the public will benefit from unrestrained competition between Remodulin® and Plaintiffs' generic treprostinil. Remodulin® is one of the most expensive drugs that is covered by insurance. For example, the average annual cost for Remodulin® treatment under Medicare Part D, per patient, was **$178,336.51** in 2015, **$150,347.14** in 2016, and **$115,030.47** in 2017. Glass Decl., Ex. I. Under Medicare Part B, the average annual cost per patient during that same time period was **$144,174.23** in 2015, **$145,129.52** in 2016, and **$146,316.70** in 2017. Glass Decl., Ex. J. Plaintiffs anticipate that the introduction of generic treprostinil will drive those costs down—potentially saving the healthcare system tens to hundreds of millions of dollars each year. deGoa Decl. ¶ 8. Expanding the

availability of generic treprostinil would therefore benefit patients, healthcare providers, and payers by substantially reducing the cost of care.

II. Plaintiffs' Proposed Discovery Requests Are Reasonable and Necessary to Provide the Court with a Fulsome Factual Record

While the foregoing showing is already strong, Plaintiffs nonetheless seek early and expedited discovery to help them prepare their motion for preliminary injunctive relief. "Expedited discovery has been ordered where it would better enable the Court to judge the parties' interests and respective chances for success on the merits at a preliminary injunction hearing." *Better Packages,* 2006 WL 1373055, at *3 (quotations omitted). That is the case here. Certain information that could prove to be material to the preliminary injunction proceedings is exclusively within the control of Defendants, and Plaintiffs seek leave from the Court to pursue discovery of that information to ensure the Court receives the benefit of a developed record when weighing the merits of their forthcoming motion.

As courts in this district have recognized, "expedited discovery is particularly appropriate when a plaintiff seeks injunctive relief because of the expedited nature of injunctive proceedings." *Better Packages*, 2006 WL 1373055, at *3 (quotations omitted). So long as discovery requests are "narrowly tailored to fit the needs of a preliminary injunction hearing, leave to conduct expedited discovery should be granted." *Id.*; *see also Chubb Ina Holdings*, 2016 WL 3470291, at *4 (accord). Applying that test, courts within the Third Circuit routinely permit expedited

discovery in preparation for a preliminary injunction hearing. *See, e.g.*, *Nest Int'l*, 2012 WL 1584609, at *2; *Kone Corp. v. ThyssenKrupp USA, Inc.*, Civ. Action No. 11-465-LPS-CJB, 2011 WL 4478477, at *6 (D. Del. Sept. 26, 2011); *EXL Labs., LLC v. Egolf*, Civil Action No. 10-6282, 2010 WL 5000835, at *8 (E.D. Pa. Dec. 7, 2010).

Plaintiffs' proposed discovery requests are reasonable and limited to the matters that will be material to the preliminary injunction hearing. Plaintiffs' motion would benefit from certain material facts that are exclusively within the Defendants' possession, and it is that information that is targeted by Plaintiffs' proposed discovery. Specifically, with leave from the Court, Plaintiffs would propound discovery requests to ascertain (1) the precise restrictions Defendants have adopted and how much of the market they have affected; (2) how those restrictions have been communicated to specialty pharmacies and patients; (3) the underlying rationale—pretextual or otherwise—for adopting the restrictions; and (4) when the restrictions were first adopted. *See* Glass Decl., Ex. K (Plaintiffs' Proposed Discovery Requests). As things stand, the only information Plaintiffs have received on each of these topics is from second-hand sources in the marketplace. Absent discovery concerning these topics, it will be difficult for the Court to assess the parties' relative chances of success when weighing the merits of Plaintiffs' forthcoming motion. Discovery will therefore focus on the factual evidence that will be presented at the

preliminary injunction hearing. *See, e.g.*, *Kone Corp.*, 2011 WL 4478477, at *7 ("[C]ourts have regularly noted that expedited discovery is more likely to be an efficient use of the parties' resources when it relates to a pending preliminary injunction hearing, where it can help to ensure a clear and focused factual record.").

Plaintiffs' proposed discovery requests will not impose an undue burden on Defendants. Plaintiffs have narrowly tailored their requests to seek only the information they need for the preliminary injunction, and nothing more. All of the topics addressed by Plaintiffs' proposed discovery requests relate to material evidence that Defendants will need to present when opposing the requested injunction. Asking them to gather and produce that information to Plaintiffs a few weeks in advance of the preliminary injunction hearing is not unreasonably burdensome. To the contrary, it will promote efficiency by narrowing the issues that must be addressed by the Court before ruling on Plaintiffs' motion.

Moreover, as reflected in their proposed order, Plaintiffs will stipulate to reasonable limitations on the scope of expedited discovery. By way of example, Plaintiffs' proposed order provides for no more than five non-expert depositions per side, a truncated process for preparing expert disclosures, no more than ten interrogatories per side, and no more than twenty document requests per side. Under the circumstances, those limitations strike a reasonable balance—they will allow

Plaintiffs to obtain the information they need without imposing an unfair burden on Defendants.

III. A Scheduling Order for Plaintiffs' Forthcoming Motion for a Preliminary Injunction Is Warranted

As soon as Plaintiffs have obtained the benefit of the discovery described above, they will file a motion seeking a preliminary injunction. Plaintiffs respectfully request an order that establishes an orderly schedule for briefing and argument on that motion. Plaintiffs' proposed schedule, subject to the Court's approval, is reflected in the table below:

EVENT	DATE
Service of interrogatories and requests for production	Within 4 days after entry of the scheduling order
Responses and objections to written discovery	Within 1 week after service of written discovery
Completion of document productions	Within 2 weeks after responses and objections to written discovery
Completion of non-expert depositions	Within 3 weeks after completion of document productions
Exchange of expert reports	Within 1 week after completion of non-expert depositions
Completion of expert depositions	Within 2 weeks after exchange of expert reports

Plaintiffs' motion for preliminary injunction	Within 1 week after completion of expert depositions
Defendants' opposition	Within 1 week after motion for preliminary injunction
Plaintiffs' reply brief	Within 5 days after Defendants' opposition
Preliminary injunction hearing	The Court's earliest available date after August 1, 2019

CONCLUSION

For all of the reasons stated herein, Plaintiffs respectfully submit the Court should grant Plaintiffs' application for an Order to Show Cause and require Defendants to show cause, no later than 5 calendar days of entry of the Court's Show Cause Order, for why (1) early and expedited discovery should not be granted; and (2) a scheduling order for briefing and argument concerning Plaintiffs' forthcoming motion for a preliminary injunction should not be issued.

Dated: April 19, 2019 Respectfully submitted,

By: */s/ Thomas D. Pease*

QUINN EMANUEL URQUHART & SULLIVAN, LLP
Thomas D. Pease (NJ Bar No. 055421994)
Peter Calamari (*pro hac vice* application pending)
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000 (Phone)
thomaspease@quinnemanuel.com
petercalamari@quinnemanuel.com

Ethan C. Glass (*pro hac vice* application pending)
Michael D. Bonanno (*pro hac vice* application pending)
1300 I Street NW, Washington, DC 20005
(202) 538-8000 (Phone)
ethanglass@quinnemanuel.com
mikebonanno@quinnemanuel.com

Attorneys for Plaintiff RareGen, LLC

By: */s/ Jenny Kramer*

ALSTON & BIRD LLP
Jenny Kramer (NJ Bar No. 014372001)
90 Park Avenue 15th Floor
New York, NY 10016
(212) 210-9400 (Phone)
Jenny.Kramer@alston.com
Michael P. Kenny (*pro hac vice* application pending)
Matthew D. Kent (*pro hac vice* application pending)
Allison S. Thompson (*pro hac vice* application pending)
Jonathan D. Parente (*pro hac vice* application pending)
1201 West Peachtree Street, Suite 4900
Atlanta, GA 30309
(404) 881-7000 (Phone)
Mike.Kenny@alston.com
Matthew.Kent@alston.com
Allison.Thompson@alston.com
Jonathan.Parente@alston.com

Attorneys for Plaintiff Sandoz Inc.